Technology Assessment Program

Office of Patient Care Services

UPDATED INFORMATION FOR VA TECHNOLOGY ASSESSMENT PROGRAM (VATAP) REPORTS

In June 2000, VATAP was relocated within the Veterans Health Administration from the Office of Research & Development to the Office of Patient Care Services. The following report was produced prior to the relocation of VATAP.

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VA TECHNOLOGY ASSESSMENT PROGRAM
SHORT REPORT– *Optical Lens Fabrication System*

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Executive Summary

Expansion of Veterans Health Administration (VA) eligibility criteria and emphasis on preventive services reinforces the challenge in VA to provide access to quality prescription eyewear. Lowering costs and preserving quality eyeglass products are two of many initiatives underway to improve visual services to veterans.

Recent advances in optical materials and manufacturing processes make it possible to produce prescription eyewear in-office. Several products are now available that claim the ability to produce high volume, high quality and low cost lenses for a range of prescription needs.

The Clinical Manager of Veterans Integrated Service Network (VISN) 7 asked the MDRC Technology Assessment Program to evaluate one such product from Optical Dynamics Corporation called the Q-2100™ Lens Fabrication System. The MDRC systematically reviewed the peer-reviewed published evidence to assist VISN 7 with their goal of providing high quality eyewear to veterans for less cost.

Extensive database and web searches indicate that comparative study of various in-office lens fabrication systems on cost, quality or other benefits is confined to product literature. The search results do call attention to problems within the optical industry in maintaining prescription quality.

VA experience with the Q-2100™ is confined to the Washington DC VAMC Optical Service since November 1999. They purchased the Q-2100™ for $38,000 and produce lenses of very high optical quality for as little as $10 to $25 per pair on average (lens materials only). Anecdotal evidence suggests that they may be able to fill a significant percentage of prescriptions in-house. Patient satisfaction with prescriptions is high, and waiting times and administrative paperwork resulting from equipment acquisition and service reorganization have been significantly reduced. The ability to now offer emergent prescription refills to inpatients is key.

Across VA facilities there are differences in the structure of Optical Services and in the patients they serve. Therefore, other facilities may not experience the cost savings and other benefits associated with Q-2100™ that the Washington VAMC has reported by switching to in-house production.

A facility must be able to compare the total in-house costs of a pair of glasses using the Q-2100™ to total contract costs to determine cost savings. Total in-house costs should include fitting, lenses, frames, FTEE required to manufacture lenses, administrative costs, dispensing and follow-up.

Industry and VA experiences indicate that in addition to adhering to FDA safety regulation and existing industry standards, operator training and point-of-care quality assurance practices are essential to assuring prescription accuracy.

Background

The Veterans Health Care Eligibility Reform Act of 1996 has had a dramatic, yet predictable, effect on the provision of vision services in VA (VHA 1996). New criteria expanded the number of eligible veterans in the system and lowered the threshold of eligibility for eyeglasses. From 1993 to 1998 the number of patients increased 40% and the number of eyeglasses dispensed increased 128%, while combined staffing for eyecare rose only 11% (Montrey 1999).

In Fiscal Year 1998 VA dispensed 327,717 pairs of eyeglasses at a total cost of $15,616,213 to the system and at a national average unit cost of $47.65 (personal communication: Dr. J. Orcutt, 2/9/2000). Several efforts are underway in VA to address the mounting challenges to preserve vision services for

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its veterans (Montrey 1999). This review addresses one effort to reduce the cost of eyeglasses dispensed to veterans.

The Clinical Manager of VISN 7 asked the MDRC Technology Assessment Program to evaluate the Q-2100™ Lens Fabrication System from Optical Dynamics Corporation (Louisville, KY), an in-office plastic eyeglass lens manufacturing system. VISN 7 supplied the following information as background to the request:

"We have been looking at ways to decrease our costs in providing eyeglasses for our veterans. To this point we have established a network contract with a commercial vendor. One of our hospitals is interested in taking over this process based on recent advances in the fabrication process in making glasses."

"We were paying an average of $61.00 a pair for glasses prior to the contract. Now the price is averaging $37.75, thus a savings of approximately $23.00 a pair. Delivery time to the veteran is 7 days after [the] prescription is faxed to [the] vendor."

"…What we would be interested in is if an evaluation has been completed of this vendor's product or if one could be done."

"…The Washington D.C. VA recently opened an optical shop in the medical center. They are making spectacles on site using a new molding technology."

This review will address the following questions:

- What is the published evidence on the cost of and quality of product from the Q-2100™?
- How does the Q-2100™ compare to the existing contract or to other in-office lens fabrication systems?
- Are there other potential benefits of the Q-2100™?

Description of the device

Optical Dynamics Corp. (ODC) product literature describes the Q-2100™ as a microprocessor-controlled in-office whole lens casting system that uses a proprietary liquid lens monomer to produce a variety of lens designs. The Q-2100™ series offers progressive, flat-top bifocals and aspherics in both single visions and progressives in clear plastic, high index and Phases photochromic.

Q-2100-R™ is the subject of this review. It requires one operator to manufacture on average three to four pair of lenses per hour.

Regulation and industry recommendations

U.S. Food and Drug Administration (FDA 1999) requires compliance with minimum strength safety requirements for impact resistance. There are no other required compliance standards.

Industry recommends compliance with the American National Standards Institute (ANSI®) Z80.1 standard for dress eyewear for measuring prescription accuracy (Optical Laboratories Assn. 1995). The standard "provides quality goals for new and pristine lenses prepared to individual prescription" comprising sphere, cylinder, axis, vertical imbalance, add power and cosmetic quality.

COLTS℠ Laboratories (Clearwater, FL) was established three years ago in recognition of an industry need for tighter quality assurance controls. COLTS℠ is the only independent testing laboratory for ophthalmic lenses in the country. They provide performance and prescription testing for retail stores and wholesale labs, but as yet no professional or industry organization has required COLTS℠ certification (personal communication: John Young, COLTS℠ Laboratories, 1/28/00).

ODC reports that the Q-2100™ is the only device to have received COLTS℠ certification seals for both Product Performance (manufacturing) and Prescription Accuracy. This indicates that the Q-2100™ meets COLTS℠ minimum performance requirements with at least a 90% acceptable product yield in accordance with FDA safety regulations and ANSI® Z80.1 recommendations. ***However, lack of COLTS℠ certification does not imply that a device does not meet current standards.***

The COLTS℠ Prescription Accuracy seal certified prescription accuracy for the following lens parameters: +4.00D to –4.00D spherical out to –2.00D cylinder for lens types including single vision, straight top 28 bifocals and progressive lenses.

Potential benefits

Production. ODC reports that the Q-2100™ can produce high quality lenses for a fraction of the costs and time required by traditional surfacing, making it the most profitable and cost efficient lens system available. It uses the same process for all lens designs and requires fewer steps than conventional processing. The technician can control lens quality throughout the process. It offers user-friendly features that allow for minimal training time, low space requirements and minimum inventory. Low energy consumption and no waste byproducts make the Q-2100™ environmentally friendly.

Product. ODC product literature further emphasizes high accuracy and consistent product quality, edge to edge optical clarity, state-of-the-art aspheric designs, and thin, light, cosmetically pleasing and comfortable designs. Q-2100™ produces lens power of ±4.00D spherical (0.25D steps), –0.25D out to –2.00D cylindrical, and add power up to +3.00D.

VA Optometry Service Guidelines

A new eyecare manual for VA is currently under review.

Eligibility criteria. Eligibility criteria for eye-related appliances, devices and/or prostheses were reformed in 1996 and are particularly relevant to VA managers interested in in-office lens fabrication systems (VHA 1996):

- Any veteran with a compensable (10% or more) service-connected disability.
- Any former prisoner of war.
- Any veteran in receipt of increased pension based on the need of regular aid and attendance or by reason of being permanently housebound.
- Veterans in receipt of benefits on the basis of Title 38 U.S. Code 1151.

VISNs and/or medical facilities may provide eyeglasses to all other veterans receiving VA care if the following conditions are met:

- If the visual impairment resulted from the existence of another medical condition for which the veteran is receiving VA care or resulted from treatment of that medical condition; or
- If the veteran is so severely visually impaired that the provision of eyeglasses is necessary to permit active participation in the veteran's own medical treatment.

VA experience with Q-2100™

Personal communication with a Staff Optician and a Staff Optometrist at the Washington DC VAMC confirms the manufacturer's stated benefits in production and product (1/19/00). They offered several observations based on their limited experience with the technology since November 1999:

- Their Q-2100™ costs $38,000 and produces very high optical quality lenses for as little as $10 to $25 per pair on average. Cost comprises monomer and gaskets only. Frames cost an additional $7.97 each.
- The device is very user-friendly with a relatively short learning time (2-3 weeks), bearing in mind that their optician has 25 years of experience.
- Rejections (errors) have been minimal and have resulted from errors in residents' prescriptions rather than lens production.

Administrative and organizational changes made in conjunction with the Q-2100™ acquisition have resulted in more positive than negative effects, thus far. Most relevant is the increased convenience to staff and most patients:

- In the first two months of operation, they filled approximately 42% of their prescriptions on-site. As experience with the technology increases, estimates may be much higher.
- Patient satisfaction with their eyewear is high.
- They have reduced the waiting time for prescription fills from 4-6 weeks with an outside contractor to one week or less with the Q-2100™.
- Whereas before acquiring the Q-2100™ it was impossible to fill emergent inpatient requests, it can now be done within 1-2 hours.
- Assuming eyeglass dispensing from Prosthetics allowed them to simplify administrative paperwork for staff and patients.

There are downsides to the equipment acquisition.

- A significant portion of prescriptions still needs to be filled by contract.
- Shifting dispensing responsibilities from Prosthetics Service resulted in an increase in Optical Department personnel and administrative costs associated with fitting, dispensing and patient follow-up.

While the Q-2100™ offers an appealing potential for retail production, it is unclear whether they will expand in that direction. There are unresolved conflicts between generating revenue from the veteran population and complying with existing eligibility criteria. Practically, a retail shop in VA would need to offer a much larger frame selection than what is typically offered to veterans. Expanding frame selection would likely result in increased costs, because cutting lenses for individual frame patterns is very labor intensive.

Patient selection criteria for the device
The device's limited time on the market currently proscribes the ability to define patient selection criteria. For the Q-2100™ it is reasonable to select patients whose prescriptions are included in the range that COLTS℠ Laboratories independently tested and certified for prescription accuracy: +4.00D to –4.00D out to –2.00D cylinder for lens types including single vision, straight top 28 bifocals and progressive lenses.

Assessment Methods

The MDRC TA Program used the following search strategy to identify published research studies addressing the questions for this review.

Literature retrieval necessitated lengthy searches on all potentially useful databases with a variety of terms relevant to optical or lens fabrication systems. We performed a wide array of database (Dialog®) and web searches beginning with the traditional databases: The Cochrane Library®, MEDLINE®, EMBASE®, HealthSTAR®, Science Citation Index®, Current Contents®, and BIOSIS®.

We performed additional searches on INSPEC, NTIS©, Ei Compendex®, DISSERTATION ABSTRACTS ONLINE, Inside Conferences, International Pharmaceutical Abstracts®, HIS International Standards & Specifications, JICST-EPlus®, PASCAL®, Health Devices Sourcebook®, EPISCOM®, FDC Reports®, DIOGENES®, and Health Devices Alerts®. We included searches on AMA Journals, New England Journal of Medicine and The Lancet from issues dated February 1, 2000 through February 4, 2000.

Web searches collected information on the products themselves, enabling contacts with the industry to elicit additional published study or conference presentations references. The FDA web site supplied the Code of Regulations for product safety.

Articles meeting the following criteria were eligible for inclusion in this review:

- Peer-reviewed empirical findings of a structured comparison of Q-2100™ to other standard point of sale lens fabrication systems.
- Analyses of factors influencing manufacturing and quality of product.
- Articles published in English, or English abstract available.

For critical analysis in our systematic reviews, we typically combine included studies qualitatively to judge whether valid answers to critical assessment questions can be obtained from the research published to date.

Results

Database searches generated approximately 30 citations, of which upon close examination, none met the criteria for inclusion. Available data are confined to the product literature.

Web searching did reveal several relevant non-peer reviewed articles about problems with the quality of prescription eyewear provided by the optical industry. Popular news investigative reports from 1998 found that at least 50% of prescriptions were filled incorrectly (Diaz 2000; Witt 1998).

A comparison of prescription accuracy among military and civilian facilities in five cities revealed similar results (Mittelman 1998). These reports listed in Table 1 have been instrumental in initiating tighter quality assurance measures within the optical industry.

Table 1. Non-peer Reviewed Studies on Prescription Eyeglass Quality

Citation	Goal	Methods	Results/Conclusions
Witt (1998)	To assess accuracy of prescription eyeglasses	• Undercover shopper sent with a typical bifocal prescription to seven top optical chains in the greater New York area • Eyeglasses independently assessed by an optometrist for accuracy	All seven eyeglasses failed with regard to power, strength or overall workmanship
Diaz (2000)	To assess accuracy of prescription eyeglasses	• Several undercover volunteers examined by an optometrist, given a prescription and sent to several different stores including national chains, regional chains and neighborhood opticians • COLTS Laboratories independently assessed each pair four times for prescription accuracy	• 15 of 29 pairs judged unacceptable against industry standards • Report cited lack of training, certification or licensing required in most states • Recommended that glasses be made or at least checked by a licensed optician or one certified by the American Board of Opticianry or the American Optometric Association
Mittelman (1999)	To compare delivery times, spectacle quality and retail costs of Naval Ophthalmic Support and Training Activity (NOSTRA) system to the civilian sector	• Double-blind study • 5 cities selected secondary to accessibility to Navy optometry clinics • 6 commercial optical sources selected, majority were national chains • Standardized prescription communicated to each clinic head: OD - 3.75 - 1.75 x 135 OS - 4.00 - 2.00 x 047 Add: +2.00 OU CR-39 lenses ST-35 bifocals PD 68/66 Segment Height: 19mm PC - 250 metal frame provided by optometrist to each commercial facility • Prescription and frame ordered at each site • Dates, times and source of filled receipt annotated • All glasses checked against ANSI standards by ABO certified optician	COMMERCIAL SOURCES: • Average pick-up time=5.22 days (range 2.2-14 days) • Average delivery time=11.66 days(range 4-28 days) • Not dependent upon location of source • 92% (24 of 28) of the glasses received from commercial sources did not meet ANSI standards NOSTRA: • Average pick-up time=2.2 days • Average delivery time=9.6 days • 13% (1 of 8) of glasses fabricated at NOSTRA did not meet ANSI standards **Conclusions** • Cost data not available • NOSTRA system had faster delivery and pick-up times; quality surpasses commercial sector, but not good enough • Re-engineered Quality Control Section; Customer returns significantly reduced since inception

Summary and Discussion

The optical industry is dynamic and evolving. Advances in manufacturing and materials for plastic optics and coatings allow practitioners to produce high volume and dispense low cost, lightweight, complex corrective lenses; industry is concerned with covering costs and attaining appropriate quality (Tribastone 1995).

Quality assurance standards have been established but are not always well known or adhered to. Currently, compliance with FDA safety regulations for impact resistance is mandatory, and compliance with ANSI® industry standards is encouraged. Recent reports, which raised public awareness of the variable quality of prescription eyewear, attest to the need for tighter quality assurance within the industry. VA has played an important role in these efforts (Monaco 1998).

COLTS℠ Laboratories quality seals emphasized in ODC product literature warrants further comment. COLTS℠ Laboratories was established to provide the optical industry with an independent facility to test the capability of a device to produce lenses that meet existing industry benchmarks for minimum prescription quality. ***COLTS℠ certification does not indicate that the device or its product is superior to other similar devices, but it does signify that ODC has taken extra effort to ensure product quality.***

The learning curve may affect prescription accuracy especially in the early stages of operation. VA experiences and COLTS℠ Laboratories testing emphasized the need for operator training to minimize learning time, especially if the operator lacks optical experience. COLTS℠ indicated that training should include an understanding of prescription optics, thickness requirements and cosmetics.

Available comparative data on the cost and quality of product from relatively new plastic lens casting systems are confined to product literature. Limited evidence from industry suggests that operator training and point-of-care quality assurance practices are essential in assuring prescription accuracy.

The Washington DC VAMC Optical Service identified important benefits of the Q-2100™ to veterans. The ability to offer emergent prescription refills to inpatients is key. Anecdotal evidence suggests that patient satisfaction with their prescriptions is high, and waiting times and administrative paperwork resulting from equipment acquisition and service reorganization have been significantly reduced.

Across VA facilities, Optical Services are structured differently, and patients' needs can vary substantially. Therefore, the cost savings and other benefits associated with Q-2100™ that have been reported at the Washington VAMC may not be similarly experienced at other facilities.

To determine actual cost savings a facility must be able to compare the total in-house costs of a pair of glasses using the Q-2100™ to total contract costs. Total in-house costs should include fitting, lenses, frames, FTEE required to manufacture lenses, administrative costs, dispensing and follow-up.

The prescription range of the Q-2100™ and the impact on other eye care needs associated with in-house manufacturing should also be considered. Prescriptions outside the certified range of the Q-2100™ would need to be filled by contract, and reducing the number of lenses needing to be filled under contract may result in a higher unit cost for those lenses.

Expansion of VA eligibility criteria and emphasis on preventive services reinforces the challenge to VA to provide access to quality prescription eyewear. Lowering cost and preserving quality eyeglass products are some of the many initiatives within VA to improve visual services to veterans (Montrey 1999). VA Optical Services should consider compliance with existing FDA and ANSI® Z80.1 standards as the minimum compliance standards for quality assurance of prescription eyewear.

References

104th Congress. Accessed: February 24, 2000. ***Vererans' Health Care Eligibility Reform Act of 1996. Public Law 104-262. 110 STAT. 3177-3181***. United States Government Printing Office. [Web Site]. Available: October 9, 1996. **http://www.access.gpo.gov/nara/publaw/104publ.html.**

Diaz A, Downs H, Walters B. Accessed: February 4, 2000. ***20/20 Vision***. TV & Radio Transcripts Daily. Federal Document Clearing House. [Dialog online file 648].

Mittelman MH. *A survey of delivery times and quality of spectacles provided by commercial optical sources compared to the naval ophthalmic support and training activity*. Annual Meeting of the American Academy of Optometry, December 20, 1998.

Monaco WA, Moderator. *Are our patients getting what we prescribe?* Annual Meeting of the American Academy of Optometry, December 14, 1998.

Montrey JS. Preservation of veterans'vision. *Veterans Health System Journal* 1999; 4(11):43-46,55.

Office of Patient Care Services (112). (1997). *Optometry service guidelines for Veterans Health Administration (VHA) medical facilities.* [Web site]. Available: **http://www.va.gov/publ/direc/health/handbook/1121-1.htm**, [1/18/00].

Optical Laboratories Association. *American National Standard for Ophthalmics. Prescription Ophthalmic Lenses - Recommendations.* Report Number ANSI Z80.1-1995. 1995, Optical Laboratories Association: Merrifield, VA.

Tribastone C, Gardner C, Peck WG. Precision plastic optics applications from design to assembly. In: *Design, Fabrication, and Applications of Precision Plastic Optics*. Philadelphia: International Society for Optical Engineering, SPIE; 1995.

U.S. Food and Drug Administration. Accessed: February 1, 2000. ***Prescription spectacle lens. [Sec. 886.5844]***. U.S. Food and Drug Administration,. [Web Site]. Available: Revised as of April 1, 1999. **http://www.fda.gov/cdrh/devadvice/part886.html#contents.**

U.S. Food and Drug Administration. Accessed: February 1, 2000. ***Use of impact-resistant lenses in eyeglasses and sunglasses. [Sec. 801.410]***. U.S. Food and Drug Administration. [Web Site]. Available: Revised as of April 1, 1999. **http://www.fda.gov/cdrh/devadvice/part801.html#contents.**

Witt D. (1998). *CBS Spotlights Optical Errors.* [Web Site]. Available: **http://www.2020mag.com/issues/1998/jan/upfront.htm**, [2/4/00].

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